July 2005

Nevada State Board of Pharmacy

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Schedule of 2005 Board Meetings

July 20-21 ..... Las Vegas
September 7-8 ..... Reno
October 26-27 ..... Las Vegas
December 7-8 ..... Reno

New Executive Secretary

Larry Pinson, PharmD, has been selected to become the Nevada State Board of Pharmacy executive secretary effective September 1, 2005. Dr Pinson received his doctor of pharmacy degree from the University of California Medical Center at San Francisco, CA, in 1973.

For 21 years, and until 2001, Dr Pinson owned and operated Silverada Pharmacy in Sparks, NV. Prior to operating an independent pharmacy, Dr Pinson was employed at St Mary's Regional Medical Center in Reno, NV, as assistant director of Pharmacy Services. Most recently, Dr Pinson has been the pharmacy manager for Scolari's Food and Drug in Reno, NV.

His professional and related activities include serving as a consultant pharmacist and adjunct professor. He is also on the board of directors for Pharmaceutical Care Network, a board member of the California Alumni Association, preceptor for his county school district gifted program, member of a professional review board, and maintains various memberships in professional associations and fraternities.

In addition to operating his business or practicing as a pharmacist, Dr Pinson has served his community extensively including serving as a member of the Northern Nevada Substance Abuse Council, consultant for the National Special Olympics, director for the American Cancer Society, member of the Blood Services of Nevada and Arthritis Foundation, and on the State Medicaid Pharmacy and Therapeutic Committee. Dr Pinson is a past recipient of the Bowl of Hygeia Award and has also received a Leadership Award from the Boy Scouts of America and the Pharmacist of the Year award from the Nevada Pharmacy Alliance.

Larry Pinson's wife, Kathy, is a dental hygienist and son Scott is a structural engineer. His daughter, Kelly, is a pharmacist and must be proud her license certificate bears her father's signature as the president of the Nevada State Board of Pharmacy.

Legislation

The Board did not introduce a bill of its own in the 2005 Legislative Session. Nonetheless, several bills that impact the practice of pharmacy in Nevada did pass and will soon become law. Following is a brief summary of the pertinent bills.

Assembly Bill (AB) 195 authorizes Canadian mail-order pharmacies to become licensed by the Board to provide prescription drugs to Nevada residents. The Office for Consumer Health Assistance must establish a Web site and provide information to consumers concerning purchasing prescription drugs from the Canadian pharmacies. Important patient protections in AB 195 include that the supplied drugs:

1. Cannot be controlled substances;
2. Must be drugs approved by the federal Food and Drug Administration (FDA);
3. Must be generic drugs approved by FDA;
4. Cannot be drugs that FDA has withdrawn or suspended; and
5. Must be limited to a 90-day supply.

It remains to be seen what action, if any, FDA will take regarding AB 195.

Senate Bill (SB) 37 is a bill introduced by Senator Valerie Weiner (D-Las Vegas) to strengthen the licensure requirements and regulation of the prescription drug wholesale industry. The bill requires:

1. A criminal background check and fingerprinting of persons of significant influence in the operation of a wholesaler;

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New Board Will Oversee Management of Drug Safety Monitoring

Food and Drug Administration (FDA) has unveiled a program that aims to improve oversight of drug safety monitoring and to bolster openness in agency product review and decision making. Included is the creation of an independent Drug Safety Oversight Board, made up of medical experts from FDA and other government agencies. Also planned are Web postings of emerging drug data and risk information as well as written materials that provide targeted drug safety information to the public. For more information, see www.fda.gov/oc/factsheets/drugsafety.html.

ACPE Changes Provider Criteria Regarding Drug and Device Manufacturers

In early 2005, the Accreditation Council for Pharmacy Education (ACPE) ceased accepting applications from pharmaceutical and biomedical device manufacturers seeking accreditation as providers of continuing education (CE). Effective July 1, 2005, the organization will no longer recognize pharmaceutical and biomedical device manufacturers as accredited providers. In addition, any CE issued by a pharmaceutical or device manufacturer after June 30, 2005, is not valid. These changes were approved by the ACPE Board of Directors at its January 2005 meeting after the organization determined that manufacturers could not meet both ACPE's requirements and the recommended restrictions as stated in a Compliance Program Guidance for Pharmaceutical Manufacturers published by the Office of the Inspector General of the United States (OIG).

In 2003, OIG stated that manufacturers could be subjected to liability under federal statutory provisions if they maintain any influence over CE subject matter or presenters, or provide funding for attendees or other incentives with respect to CE attendance. Strict compliance with OIG's guidelines would relegate manufacturers to solely providing educational grants to CE providers in order to be free of liability. Meanwhile, ACPE's Criteria for Quality require that the CE provider control the content speakers or authors of a CE program, putting ACPE's requirements in opposition to OIG's guidelines; hence, ACPE, out of responsibility to health regulatory boards, the profession, and the public, must now accredit only those providers who are in compliance with the ACPE criteria and the OIG guidelines.

In accordance with ACPE's new policies, organizations with a commercial interest and any proprietary entity producing health care goods or services, with the exception of nonprofit or government organizations and non-health care-related companies, will not be eligible for ACPE accreditation status.

For more information, contact ACPE Executive Director Peter Vlasses at 312/664-3575, or via e-mail at pvlasses@acpe-accredit.org.

Let's Get to the 'Point': Prescription Misinterpretations Due to Decimal Points

This column was prepared by the Institute for Safe Medication Practices (ISMP). ISMP is an independent nonprofit agency that works closely with United States Pharmacopeia (USP) and FDA in analyzing medication errors, near misses, and potentially hazardous conditions as reported by pharmacists and other practitioners. ISMP then makes appropriate contacts with companies and regulators, gathers expert opinion about prevention measures, then publishes its recommendations. If you would like to report a problem confidentially to these organizations, go to the ISMP Web site (www.ismp.org) for links with USP, ISMP, and FDA. Or call 1-800/23-ERROR to report directly to the USP-ISMP Medication Errors Reporting Program. ISMP address: 1800 Byberry Rd, Huntingdon Valley, PA 19006. Phone: 215/947-7797. E-mail: ismpinfo@ismp.org.

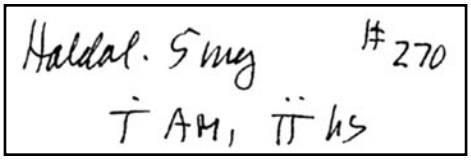
Problem: Numbers containing decimal points are a major source of error and, when misplaced, can lead to misinterpretation of prescriptions. Decimal points can be easily overlooked, especially on prescriptions that have been faxed, prepared on lined order sheets, or written or typed on carbon and no-carbon-required (NCR) forms (often used in hospitals and long-term care facilities). If a decimal point is missed, an overdose may occur. The importance of proper decimal point placement and prominence cannot be overstated.

For one, a decimal point should always be preceded by a whole number and never be left "naked." Decimal expressions of numbers less than one should always be preceded by a zero (0) to enhance the visibility of the decimal. For example, without a leading zero, a prescription for "Haldol® .5 mg" (see image shown on next page) was misinterpreted and dispensed as "Haldol 5 mg." We have received similar reports with Risperdal® (risperidone) in which "Risperdal .5 mg" was prescribed (instead of Risperdal 0.5 mg), but the patient received several 5 mg doses because the decimal point was overlooked.

In addition, a whole number should never be followed with a decimal point and a zero. These "trailing zeros" (eg, "3.0") are a frequent cause of 10-fold overdoses and should never be used. For example, when prescriptions have been written for "Coumadin® 1.0 mg," patients have received 10 mg in error. Similarly, a prescription for "Synthroid® 25.0 mcg" could be misread as "Synthroid 250 mcg."

Dangerous use of decimals can also be problematic if they appear in electronic order entry systems or on computer-generated labels. A newly admitted hospital patient told her physician that she took Phenobarbital® 400 mg PO three times daily. Subsequently, the physician wrote an order for

the drug in the dose relayed by the patient. A nurse saw the prescription vial and verified that this was the correct dose. However, prior to dispensing, a hospital pharmacist investigated the unusually high dose. When he checked the prescription vial, he found that it was labeled as "phenobarbital 32.400MG tablet." The label indicated that 30 tablets were dispensed with instructions to take one tablet three times daily. The hospital pharmacist contacted the outpatient pharmacy and suggested that the computer expressions including trailing zeros be changed to avoid serious medication errors. The pharmacy management agreed that trailing zeros appearing on labels might pose a risk and made the change immediately.



Safe Practice Recommendations

In order to avoid misinterpretations due to decimal point placement, pharmacists should consider the following:

- Always include a leading zero for dosage strengths or concentrations less than one.
- Never follow a whole number with a decimal point and a zero (trailing zero).
- Educate staff about the dangers involved with expressing doses using trailing zeros and naked decimal points.
- Eliminate dangerous decimal dose expressions from pharmacy and prescriber electronic order entry screens, computer-generated labels, preprinted prescriptions, etc.
- Avoid using decimals whenever a satisfactory alternative exists. For example, use 500 mg in place of 0.5 gram, 125 mcg instead of 0.125 mg, or 2 ½ mg instead of 2.5 mg.
- Identify drugs with known 10-fold differences in dosage strength (eg, Cytomel® 5 mcg and 50 mcg, Coumadin 1 mg and 10 mg, levothyroxine 25 mcg and 250 mcg) and place reminders in electronic order entry systems and on pharmacy shelves to alert practitioners to double-check the dosage strength.
- When sending and receiving prescriptions via fax, health care practitioners should keep in mind that decimal points can be easily missed due to "fax noise." Whenever possible, encourage prescribers to give original prescriptions (with an indication that it has been faxed) to their patients to take to the pharmacy for verification. Pharmacists should carefully review faxed prescriptions and clarify prescriptions that contain fax noise.
- Eliminate the lines on the back copy of NCR forms so that a person receiving can clearly see decimal points or other marks that were made on the top copy.
- Notify prescribers of the potential for error if misinterpretations due to decimal point usage are discovered.

DEA Issues Final Rules for Electronic Orders for Controlled Substances

On April 1, 2005, Drug Enforcement Administration (DEA) issued final rules regarding electronic orders for controlled substances. DEA revised its regulations to provide an electronic equivalent to the DEA official order form (Form 222), which is legally required for all distributions involving Schedule I and II controlled substances. The regulations will allow, but not require, registrants to order Schedule I and II substances electronically and maintain the records of these orders electronically. The regulations will reduce paperwork and transaction times for DEA registrants who handle, sell, or purchase Schedule I or II controlled substances. The effective date of the final rules was May 31, 2005.

The final rules were issued via the *Federal Register* on April 1, 2005, and may be downloaded from the following Web site address: www.access.gpo.gov/su_docs/fedreg/a050401c.html.

FDA Publishes Final Rule on Chlorofluorocarbons in Metered Dose Inhalers

FDA announced that albuterol metered-dose inhalers (MDI) using chlorofluorocarbon propellants must no longer be produced, marketed, or sold in the US after December 31, 2008.

The Health and Human Services (HHS) is encouraged that the manufacturers of three environmentally friendly albuterol inhalers are implementing programs to help assure access to these albuterol MDI for patients for whom price could be a significant barrier to access to this important medicine. These programs include MDI giveaways, coupons for reducing the price paid, and patient assistance programs based on financial need.

In a final rule, published March 31, 2005, in the *Federal Register*, HHS stated that sufficient supplies of two approved, environmentally friendly albuterol inhalers will exist by December 31, 2008, to allow the phasing out of similar, less environmentally friendly versions.

FDA Develops PSAs to Educate Consumers About Purchasing Medications Online

FDA recently released two public service announcement (PSA) brochures, which educate consumers about the advantages and disadvantages of purchasing medication online. The brochures also advise consumers to ensure a Web site is a US-licensed pharmacy by contacting their state board of pharmacy. Consumers may want to refer to the list of Verified Internet Pharmacy Practice Sites™ (VIPPS®) on www.nabp.net to find out if a Web site has been checked to make sure it it has met state and federal rules. Consumers also will know if an online pharmacy is VIPPS-accredited when they notice the VIPPS Seal on that particular Web site.

For more information on these PSAs visit www.fda.gov/cder/consumerinfo/Buy_meds_online_all_resources.htm.

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2. An updated annual list of persons associated with the wholesaler;
3. An applicant or licensee upon renewal to file a bond or other form of security of as much as $100,000;
4. A statement identifying prior sales of the drug;
5. Criminal prosecution of wholesalers (Class C felony) who intentionally violate record keeping and sales prohibitions in Nevada law; and
6. Electronic pedigrees for all drugs by January 1, 2007.

Also included within this bill was an amendment concerning expiration dates on prescription container labels. The dating will be one year from the filling of the prescription, or a shorter time if the expiration date of the drug is less than the year.

SB 163 was a bill that homogenized certain administrative procedures for all licensing boards and commissions. Included within the final bill was an amendment that will require a pharmacy to transfer a prescription to another pharmacy at the request of a patient.

Prior to its final version, another amendment had been included that would have required a pharmacist to fill or refill every prescription (except prescriptions that were fraudulent, unlawful, or were contraindicated). This amendment was driven by press coverage that occurred during the Legislative Session regarding pharmacists in other states who had refused to fill certain "hot button" prescriptions (such as emergency contraception prescriptions) for reasons of the pharmacist's conscientious objection to the prescriptions.

Though this has not been a problem in Nevada, it is well to note that the issue appeared this Legislative Session and may appear in future sessions. All pharmacists need to make sure that the public (and, in particular, legislators) are aware that pharmacists are valuable and necessary providers of health care whose professional judgment and knowledge are integral to full, effective patient care. If you know or serve legislators, let them know that you can and do much more than just count by fives.

Fred T. Mahaffey Award

The National Association of Boards of Pharmacy® (NABP®) honored Nevada and two other states "for exceptional contributions in 2005 to the protection of the public health and welfare through the enforcement of federal laws and regulations, and furthering the mission of the National Association of Boards of Pharmacy." This award is the result of improved licensing and regulation of the prescription drug wholesale industry.

Recently, Health and Human Services Secretary Mike Leavitt released a final report developed by FDA that highlights specific steps the agency is taking to keep the US drug supply secure against increasingly sophisticated criminal efforts to introduce counterfeit drugs.

The Nevada State Board of Pharmacy has been one of the boards leading the nation in efforts to protect the nation's drug supply. NABP's recognition, because it is the recognition of the Board's peers, is humbling and greatly valued. Congratulations to the Board!

The *Nevada State Board of Pharmacy News* is published by the Nevada State Board of Pharmacy and the National Association of Boards of Pharmacy Foundation, Inc, to promote voluntary compliance of pharmacy and drug law. The opinions and views expressed in this publication do not necessarily reflect the official views, opinions, or policies of the Foundation or the Board unless expressly so stated.

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